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May 8, 1997

FILE: UTSK:142

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Assistant Commissioner for Patents
Washington, DC 20231

RE: *SN 07/953,680 "METHOD AND APPARATUS FOR DIRECT SPECTROPHOTOMETRIC MEASUREMENTS IN UNALTERED WHOLE BLOOD" - J. M. Steinke and A. P. Shepherd (UTHSC/SA:142)*

Sir:

Transmitted herewith for filing are:

1) A Reply Brief and Request for Oral Hearing and for Enlargement of Argument Time (an original and two copies);

2) A check for $130.00 to cover the Request for Oral Hearing filing fee; and

3) A return postcard to acknowledge receipt of these materials. Please date stamp and mail this postcard.

If the check is inadvertently omitted, or should any additional fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason relating to the enclosed materials, or should an overpayment be included herein, the Commissioner is authorized to deduct or credit said fees from or to Arnold, White & Durkee Deposit Account No. 01-2508/UTSK:142/BAH.

Respectfully submitted,

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#29 Nixon 5-20-97

In re Application of:
J. M. Steinke
A. P. Shepherd

Serial No.: 07/953,680

Filed: September 29, 1992

For: METHOD AND APPARATUS FOR DIRECT SPECTROPHOTOMETRIC MEASUREMENTS IN UNALTERED WHOLE BLOOD

Group Art Unit: 2505

Examiner: K. Hantis

Atty. Dkt. No.: UTSK:142/BAH

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#29

REPLY BRIEF
AND
REQUEST FOR ORAL HEARING AND FOR EXTENDED ARGUMENT TIME

CERTIFICATE OF MAILING
37 C.F.R. § 1.8

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on the date below:

May 8, 1997 — David D. Bahler
Date

Appellants hereby submit an original and two copies of this Reply Brief and Request for Oral Hearing and For Extended Argument Time to the Board of Patent Appeals and Interferences in response to the Examiner's Answer mailed March 14, 1997. The fee for filing the Request for Oral Hearing is $130.00 and is attached hereto.

Should such fee be deficient or absent, consider this paragraph authorization to withdraw the appropriate fee under 37 C.F.R. §§ 1.16 to 1.21 from Arnold, White & Durkee Deposit Account No. 01-2508/UTSK:142/BAH.

I. REQUEST FOR ORAL HEARING AND FOR EXTENDED ARGUMENT TIME

In accordance with 37 C.F.R. § 1.194(b), Appellants hereby request an oral hearing. The appropriate fee is attached.

Appellants further request that the Board permit 40 minutes for Appellants' argument, rather than the 20 minutes prescribed by 37 C.F.R. § 1.194(c). It is respectfully asserted that the extra time is necessary to adequately respond to the myriad rejections imposed by the Examiner under 35 U.S.C. § 112, first and second paragraphs, §132, and four independent rejections of all claims under various combinations of §§102, 103 and *res judicata*. The 42 page Final Office Action, 60 page Appeal Brief (including Appendix), and 50 page Examiner's Answer attest to the complexity of this appeal.

II. REPLY TO EXAMINER'S ANSWER

The Examiner dedicates pages 4 through 23 of the Answer to a word-for-word quotation of the Final Rejection mailed March 4, 1996. Discussion of the points raised in the Final Rejection is the subject of Appellants' main brief, and these points will not be reargued in this

paper. Instead, Appellants address only the new points of argument stated by the Examiner on pages 24-50 of the Answer.

A. Anderson *et al.* Do Not Measure Unaltered Whole Blood

In the Answer, the Examiner perpetuates her misinterpretation of the Anderson *et al.* reference by stating:

> Anderson states on page 173-174 that the purpose of the present study was to investigate the light-scattering and light absorbing properties of nonhaemolyged [sic] blood, i.e. unaltered whole blood.

Examiner's Answer, at 26 (emphasis added). The Examiner thus concludes that if a liquid suspension contains red blood cells, then it must be whole blood. This faulty logic taints all of the Examiner's rejections based on prior art.

The Examiner's conclusion is completely incorrect. In fact, in accordance with the unequivocal requirements of the present invention, unhemolyzed red blood cells in a liquid suspension are necessary, but not sufficient, to conclude that the suspension is unaltered whole blood. Rather, in accordance with the present invention, "unaltered whole blood" means "whole blood that has been neither hemolyzed nor diluted." Spec., page 13, lines 18-19. In addition, independent claim 1 (and all of dependent claims 2-36) of the present application requires the determination of "concentrations of a plurality of constituent components of unaltered whole blood of unknown composition," (emphasis added). Similarly, independent claim 37 (and all of dependent claims 38-44) requires determination of "concentrations of a plurality of k constituent components of unaltered whole blood," (emphasis added).

In response to Appellant's quotation from page 177 of Anderson *et al.* ("Fully oxygenated nonhaemolysed red cells suspended in isotonic saline were studied ...," (emphasis added)), the Examiner, without any rational basis, states that this quotation "is in reference to the hemolyzed blood that is used to compare with measurements of the nonhaemolysed blood." Examiner's Answer, at 26. Then, despite the fact that the legends of each of the graphs depicted in the figures of the Anderson *et al.* article, with the exception of Figure 5, expressly state that what was being studied were "red cell suspensions," (and it is quite likely that the measurements depicted in Figure 5 were also taken from red-cell suspensions, Schmitt 7/10/95, ¶ 6), the Examiner insists that Anderson et al., when viewed as a whole, "evaluates whole unaltered blood of unknown composition." Examiner's Answer, at 27. However, notwithstanding repeated requests for the Examiner to provide specific support for her interpretation of Anderson *et al.*, the Examiner has done nothing more than provide conclusory arguments with citations that do not support the stated proposition, or with generic citations to spans of pages within the Anderson *et al.* reference. *See e.g.,* Examiner's Answer, at 13.

Moreover, six declarations of record by independent experts in this field (all of which have been ignored by the Examiner because they are "mute", Examiner's Answer, at 24-26) attest to the fact that Anderson *et al.* do not, and in fact cannot, make measurements in unaltered whole blood. Schmitt 2/25/94, ¶ 8; Pittman, ¶ 8; Nilsson, ¶ 12; Öberg, ¶ 12; Schmitt 7/10/95, ¶ 4-14; Mountain, ¶ 14.

Further, the Examiner disregards that Mr. Charles Mountain, with full knowledge of the teachings of Anderson *et al.*, was a member of a design team responsible for developing the spectrophotometric device disclosed and claimed in the Brown *et al.* patent, and that team failed in

its attempt to devise a means of measuring multiple hemoglobin species directly in unaltered whole blood. Mountain, ¶¶ 5, 7-9.

It can thus be seen that the Examiner's erroneous conclusion that Anderson *et al.* make measurements in unaltered whole blood of unknown composition can be reached only by completely ignoring strong and unequivocal evidence to the contrary. The Examiner reached this conclusion not only by ignoring the express language in Anderson *et al.*, but also by ignoring all of the eleven declarations of record.[1]

B. Brown Does not Measure Whole Blood

The Examiner, for the first time, contends that Brown *et al.* "discloses measurement of 'whole blood'", Examiner's Answer, at 29, and that, in the Examiner's opinion, this eliminates much of the "distinction between the blood tested by Brown and that of the instant claims." *Id.*

What the Examiner ignores is the words of the claims. Specifically, independent claims 1 and 37 each require irradiating a sample of "unaltered whole blood," and the detection of radiation intensities "after passing through" the sample of unaltered whole blood. These steps are completely absent from the teachings of Brown et al. because, as emphasized extensively in Appellant's main brief, Brown *et al.* hemolyze the blood sample before optical measurements are made. See Brown *et al.*, col. 6, lines 41-43; col. 8, lines 2-4 and 21-22; col. 10, lines 8-9; col. 13, lines 55-68; col. 14, lines 16-17; col. 15, line 43; col. 16, lines 8 and 40; col. 17, lines 6 and 37; and col. 18, lines 9 and 36-37. Schmitt 7/10/95, ¶ 17; Mountain, ¶¶ 11, 13.

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[1] It is also noted that, despite a written request by Appellants (in the Request for Reconsideration, 12/15/94 at 16) that the Examiner provide an affidavit under 37 C.F.R. §1.107 in support of the Examiner's contention that the dependent claims of this case are obvious over Anderson *et al.*, because they are "a matter of design engineering," no affidavit has ever been provided.

To conclude, as the Examiner does, that Brown *et al.* is indistinguishable from the claims on appeal because Brown *et al.* make measurements on unaltered whole blood, is simply without reason.

C. The Examiner's Disregard of Commercial Success is Wrong

The Examiner dedicates pages 34 to 38 of her Answer in an attempt to justify ignoring the remarkable commercial success of the present invention. The Examiner's reasoning is flawed.

First, the Examiner addresses the supplemental declaration of Dr.. Shepherd, signed August 14, 1995, and states that "gross sales figures do not show commercial success absent evidence as to market share." Examiner's Answer, at 34. The Examiner is incorrect.

Specifically, where, as here, commercialization of an invention, which has indicated dramatic sales increases over a very short period of time, is indicative of the beginnings of a "rush to the invention [that is] probative of non-obviousness." *Nichola v. Peterson*, 580 F.2d 898, 914 (6th Cir. 1978) (opinion by Judge Markey, then Chief Judge of the C.C.P.A., sitting by designation). Thus, the Examiner's position that evidence of commercial success is unworthy of consideration, absent proof of market share, is without basis.

Next, the Examiner ignores the evidence of commercial success because, "No evidence has been shown to support that only the claimed features are what is enabling the commercial success." Examiner's Answer, at 35, emphasis added. This is a fundamental misstatement of the law. In fact, all that is required to take commercial success into consideration is evidence of commercial success and a connection between the claimed invention and that success, which

support the conclusion of nonobviousness in this case. *Specialty Composites v. Cabot Corp.*, 845 F.2d 981, 991 (Fed. Cir. 1988). Here, the evidence establishes that the AVOXimeter 1000 embodies at least claim 1[2] of the present application, and that claim 1 embodies the core functions of the product. Shepherd 8/14/95, ¶ 2. In such a case, "*prima facie* evidence of nexus is established if there was commercial success and if the invention disclosed in the patent was that which was commercially successful." *Ryko Manufacturing Co. v. Nu-Star, Inc.*, 950 F.2d 714, 719 (Fed. Cir. 1991); *see also, Dmaco Corp. v. F. Von Langsdorff Licensing Co. Ltd.*, 851 F.2d 1387, 1392 (Fed. Cir.) *cert. denied*, 488 U.S. 956 (1988).

The Examiner also continues to disregard the commercial success of the present invention evidenced by the licensing of the invention before any patent has issued. Examiner's Answer, at 35-38. As explained in great detail in various declarations filed by Dr. Shepherd, the license with Instrumentation Laboratory Company expressly defines the patent and know how rights conveyed to include the information and discoveries described in the present patent application (U. S. Patent Application SN 07/953,680). Shepherd 8/14/95, ¶ 6. Thus, the technology being licensed is the very technology that is the subject matter of the claims of this appeal.

The Examiner also contends,

> Licensing programs may succeed for reasons unrelated to the unobviousness of the product or process *e.g.* license is mutably [*sic*] beneficial or less expensive then [*sic*] defending infringements [*sic*].

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[2] The Examiner makes much of the fact that Dr. Shepherd avers that "at least claim 1" of the present application is embodied in the commercial product. Examiner's Answer, at 36. This statement simply means that other claims in the application may also be embodied in the commercial product (Shepherd 8/14/95, ¶ 2), but for the purposes of demonstrating commercial success, the elements of claim 1 are sufficient.

Examiner's Answer, at 36. In response, Appellants observe that all licenses are mutually beneficial to the contracting parties, and that fact cannot render the license unworthy of consideration. In addition, Appellants observe that no patent has yet issued, and thus there could have been no charges of infringement, and thus no reason for the licensee to defend itself. The Examiner continues by speculating that,

> The commercial success may have been attributed to extensive advertising and a position as a market leader before the introduction of the product success may be attributed to related technology; consumer demand.

Examiner's Answer at 36. In response, Appellants emphasize that the commercial success of the AVOXimeter 1000 product has been realized without the use of distributors and using only direct mail advertising. Shepherd 8/14/95, ¶¶ 3-5, Shepherd 10/16/96, ¶¶ 2-5. Further, Appellants observe that AVOX Systems, Inc. was established in 1977, and that the AVOXimeter 1000 was its first clinical product, and wasn't commercialized until 1993. Shepherd 12/12/94, ¶¶ 1,3. AVOX Systems was thus not a market leader before introduction of the product. Next, the AVOXimeter 1000 is not sold with any related technology, as was made apparent by the demonstration of the AVOXimeter 1000 to the Examiner on January 19, 1994, and as reflected in the brochure appended to Dr. Shepherd's declaration of 12/94. Finally, Appellants readily admit that "consumer demand" has been directly responsible for the commercial success of the AVOXimeter 1000, just as it is directly responsible for the commercial success of all successful products.

Next, the Examiner contends that there are other features in the AVOXimeter 1000 that may possibly be responsible for commercial success. Examiner's Answer, at 36-37. Specifically, the Examiner mentions: the casing, the circuitry, the disposable cuvettes, the

calibration feature, the display, the menu driven operations, the physical dimensions, the light weight, and the printer port.

Among these, Appellants observe that the small physical dimensions of the casing, and the light weight of the AVOXimeter 1000, are advantages that flow directly from the claimed invention which, as emphasized in the background portion of the specification, eliminates the need for bulky pumps, plumbing, hemolyzers and diluters. Spec., p.8, lines 27-32. Appellants also note that the circuitry contained in the AVOXimeter 1000 (which is shown, in block diagram form, in Fig. 6 of the present application), is what permits the AVOXimeter 1000 to perform the functions described in the claims on appeal.

Next, Appellants assert that the cuvettes also are important to the practice of the present invention, because it is the cuvette that establishes the depth of the sample which, according to claim 1, is "chosen to minimize radiation scattering of undiluted whole blood."

This leaves only the calibration feature, the display, the menu driven operations, and the printer port. Appellants assert that these features are tangential to the core functions of the product, and exist, in one form or another, in prior art hemoglobinometer equipment. It is thus unreasonable to conclude that commercial success is some how due exclusively to these features. At the very least, a *prima facie* case exists establishing a nexus between the claims on appeal and the commercial embodiment of the invention, and the Examiner's ignorance of that commercial success is in error.

Lastly, in response to Appellants' proof of long felt and unsatisfied need, the Examiner states,

> there is no objective evidence to support that the problem of hemolyzing blood existing [sic] in the art for a long period of time.

Examiner's Answer, at 38. Appellants note that the evidence of record includes the unequivocal statements by two independent third party experts in the field, with personal knowledge of this long felt and unsatisfied need (Mountain, ¶¶ 7-11, Scecina, ¶¶ 7-8). Thus, the Examiner's contention that there is "no objective evidence," is just plain wrong.

The Examiner, in her Answer, continues improperly to ignore this strong, unrefuted evidence of secondary considerations, and once that evidence is properly considered, patentability of the present invention is clear.

D. The Claims are Enabled and No New Matter Has been Added

Finally, the Examiner asserts, in support of the rejection of claims 37-44 under 35 U.S.C. § 112, first paragraph, that,

> the exact number and assigning of n, k, and n-k is not found anywhere in the original specification, claims and drawings, therefore, the new matter rejection of this Office Actin still stands.

Examiner's Answer, at 46. In response, Appellants note that, despite a lengthy discussion of the "absorbance subset" and "scattering subset" terminology used in the specification, the Final Rejection specifically identified only claims 37 and 38 as not being in compliance with 35 U.S.C. § 112, first paragraph. Final Office Action, at 3-4 (¶¶ J and K). Neither of these claims say anything about an absorbance subset or a scattering subset of wavelengths. Rather, these claims recite the integers n and k, and the difference n - k, and are virtually literally supported by the specification, as originally filed, which states,

> n measuring wavelengths are employed to measure k constituent components, with n > k, thereby creating an overdetermined system of equations with respect to the chemical compounds being measured. The n - k extra equations provide a means by which errors due to n - k scattering factors can be compensated.

Spec., at p. 20, lines 24-29. The Examiner's rejection of claim 37 as not being enabled is thus unfounded.

Next, dependent claim 38 recites the calculation of a vector of n optical densities, and the use of these optical densities in a set of n linear equations to calculate the concentrations of the k constituent components. Claim 38 is supported by the specification as originally filed, for example, at page 20, line 24 to page 21 line 20. There it is explained that n simultaneous equations (shown for example at the top of page 21) are used to solve for the concentrations of the k constituent components. In particular, the concentrations of the k components appear, for example, in the equation on line 16 of page 21.

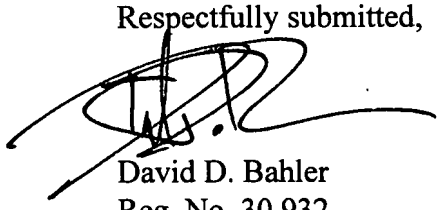
Thus, the new issues raised in the Examiner's Answer do nothing to avoid reversal of the rejection of claims 37-44 under 35 U.S.C. § 112, first paragraph.[3]

[3] The other objections to the specification and rejections of claims under 35 U.S.C. §§ 112, first and second paragraph, and § 132 are treated in Appellants' main brief.

III. CONCLUSION AND RELIEF REQUESTED

Appellants believe the foregoing Reply to respond fully to all of the new arguments raised in the Examiner's Answer, and believe that this Reply and Appellants' main brief respond fully to all of the rejections stated in the Final Rejection. The Board is respectfully requested to reverse all of the rejections stated in that Final Rejection, thus permitting the issuance of a timely Notice of Allowance for claims 1-44.

Respectfully submitted,



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